

MAY -1 2001

K011093

9.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this premarket notification is:

Dave Osborn
Regulatory Affairs Engineer
Healthcare Solutions Group
Agilent Technologies
3000 Minuteman Road
Andover, MA 01810-1085

Tel: 978 659 3178
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Email: dosborn@agilent.com

This summary was prepared on April 9, 2001.

2. The name of this device is the AIC Software Release D.O.
Classification names are as follows:

Device Panel	Classification	ProCode	Description
Panel 74 Cardiovascular	None	74 MHX	Physiological Monitor, Patient Monitor
	870.1025, III	74 DSI	Arrhythmia Detector and Alarm
	870.1025, III	74 MLD	Monitor, ST Alarm
	870.2800, II	74 DSH	Recorder, Magnetic Tape, Medical
	870.2910, II	74 MSX	Radio frequency physiological signal transmitter and receiver

3. The new device is substantially equivalent to the previously cleared HP CentralVue Software device marketed pursuant to K964832, K993907, K993171, and K001057 and to the previously cleared M1490A Wireless Patient Data Communicator K945277 as well as the StatView System, K990378.
4. The modification is a software-based change that integrates StatView Software into the central station.
5. The new device has the same intended use as the legally marketed predicate devices. They are used to display physiologic waves, parameters and, trends, to format data for compliant strip chart recorders, to format data for printed reports, and the secondary annunciation of alarms for up to 16 patients from other networked medical devices at a centralized location. To provide retrospective review of alarms, physiologic waves and parameters. And to provide primary annunciation of alarms, and configuration and control access for networked telemetry monitors at a centralized location.
6. The new device has the same technological characteristics as the legally marketed predicate devices.

7. Verification, validation, and testing activities established the performance, functionality, and reliability characteristics of the new device with respect to the predicates. Testing involved system level tests, integration tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate devices and test results showed substantial equivalence. The results demonstrate that the integrated StatView software functionality meets all reliability requirements and performance claims.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Dave Osborn
Regulatory Affairs Engineer
Agilent Technologies, Inc.
Healthcare Solutions Group
3000 Minuteman Road
Andover, MA 01810-1099

Re: K011093

Trade Name: Agilent Technologies Information Center (AIC) Software
Release D.0 StatView Software
Regulatory Class: III (three)
Product Code: 74 MHX
Dated: April 9, 2001
Received: April 10, 2001

Dear Mr. Osborn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

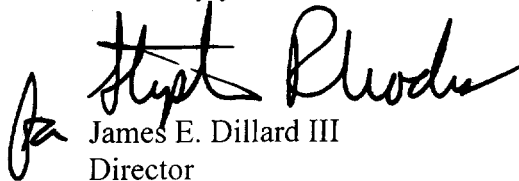
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "James E. Dillard III", is written over the typed name. To the left of the signature is a small, stylized handwritten mark that looks like "ja".

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

510(k) Number (if known): K011093

Device Name: Agilent Information Center Software, Release D.0


Indications for Use: For central monitoring of adult, pediatric, and neonatal patients; and where the clinician decides to monitor cardiac arrhythmia of adult, pediatric, and neonatal patients and/or ST segment of adult patients to gain information for treatment, to monitor adequacy of treatment, or to exclude causes of symptoms.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-The-Counter Use**
(Per 21 CFR 801.109)

(Optional Format 1-2-96)


Division of Cardiovascular & Respiratory Devices
510(k) Number K011093